UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,207	03/18/2004	Guy Rome	480062003900	5855

25224 7590 09/19/2005

MORRISON & FOERSTER, LLP
555 WEST FIFTH STREET
SUITE 3500
LOS ANGELES, CA 90013-1024

EXAMINER	
CRAIG, PAULA L	
ART UNIT	**PAPER NUMBER**
3761	

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/803,207	ROME ET AL.	
	Examiner	Art Unit	
	Paula L. Craig	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/19/04,5/13/2005*. 7/29/2005, 8/11/2005
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to because one of the occurrences of reference number 20 in Fig. 2 lacks a lead line. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

2. Claims 2, 3, and 4 are objected to because of the following informalities: In Claim 2, it is not clear whether the first lumen of the catheter is the same as or different from the first lumen of the catheter tube of Claim 1. In Claim 3, it is not clear whether the attachable bifurcation is the same as or different from the attachable unit or accessing device of Claim 1. For Claim 4, it is not clear whether the safety valve is the same as or different from the compression sleeve of Claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,785,694 to Cohen et al.

5. For Claim 1, Cohen teaches a valved catheter (Fig. 1 and col. 3, lines 21-25). The catheter has a catheter tube (tube 58, Figs. 1, 3, 5, and 7-8, and col. 4, lines 29-34). The catheter has a compression sleeve (compression member 62, Fig. 5, col. 4, lines 34-38, col. 6, lines 27-29, and col. 7, lines 24-30). The catheter tube has at least one lumen (see Fig. 8). The catheter tube has a necked portion formed in a proximal end thereof (see Fig. 3). The compression sleeve is positioned around the necked

portion (Figs. 3 and 5 and col. 4, lines 34-45). The at least one lumen is biased in a closed position at the necked portion by the compression sleeve (Figs. 3, 5, and 7-8, col. 4, lines 34-45, col. 6, lines 22-29, and col. 7, lines 24-30). The phrase "wherein said at least one lumen assumes an open position when an attachable unit or accessing device is inserted through said necked portion" is considered by the Examiner to be functional language of little patentable weight in an apparatus claim. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987), and *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967). Cohen is silent as to the at least one lumen assuming an open position when an attachable unit or accessing device is inserted through the necked portion; however, it appears that the lumen of the compressible tube 58 of Cohen is capable of assuming an open position when an attachable unit or accessing device (such as a syringe or guidewire) is inserted through the necked portion.

6. For Claim 2, Cohen teaches the catheter comprising a first lumen and a second lumen separated by a septum along a length of the catheter tube. The first lumen is the lumen of tube 58 of Cohen, as described above in paragraph 5; the second lumen is the lumen of the balloon inflation fluid passage 86; see Figs. 3 and 6-8 and col. 5, line 50 to col. 6, line 19. Note that the claim does not specify the thickness of the septum in relation to the lumens, nor that the entirety of the catheter tube must be compressed in the compression sleeve.

7. For Claim 3, Cohen discloses the valved catheter being attached to an attachable bifurcation (Fig. 2 and col. 4, lines 1-25). The attachable bifurcation provides substantially unobstructed flow of a fluid from the attachable bifurcation to the catheter tube (col. 4, lines 6-14).

8. For Claim 4, Cohen discloses the necked portion comprising a safety valve with substantially zero dead space (Figs. 3 and 5). While Cohen is silent as to the dead space of the valve, the valve of Cohen operates by compression of a tube in a way similar to the valve disclosed by Applicant as suitable for the invention and described by the Applicant as having substantially zero dead space (see Applicant's specification, Figs. 1-3 and paragraphs 21 and 23). Therefore, absent evidence to the contrary, the valve taught by Cohen is presumed to have substantially zero dead space. A valve with substantially zero dead space is considered by the Examiner to be inherent in Cohen. *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980).

9. For Claim 5, Cohen teaches the compression sleeve comprising a compression ring and a compression wedge (see ring-shaped compression member 62 and thickened portion 90 of Fig. 5, and col. 6, lines 27-34).

10. Claims 1 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,895,376 to Schwartz et al.

11. For Claim 1, Schwartz teaches a valved catheter (Figs. 1 or 2 and col. 3, lines 12-17). The catheter has a catheter tube (collapsible membrane 22, Figs. 1 or 2, col. 3, lines 18-29, and col. 4, lines 11-12). The catheter has a compression sleeve (chamber

30 and elastomeric sleeve 44 in the embodiment of Fig. 1; chamber 30, tube 54, and clamp 60 in the embodiment of Fig. 2; see col. 3, lines 30-57 and col. 4, lines 11-21). The catheter tube has at least one lumen (Figs. 1 or 2). The catheter tube has a necked portion formed in a proximal end thereof (Figs. 1 or 2). The compression sleeve is positioned around the necked portion (Figs. 1 or 2). The at least one lumen is biased in a closed position at the necked portion by the compression sleeve (col. 3, lines 40-42, and col. 4, lines 12-14). The at least one lumen assumes an open position when an attachable unit or accessing device is inserted through the necked portion (see operating device 19, Figs. 1 or 2, col. 3, lines 17-29, and col. 4, lines 17-18).

12. For Claim 7, Schwartz teaches the compression sleeve being made of silicone. See elastomeric sleeve 44 and tube 54, Figs. 1 and 2, col. 3, lines 47-51, and col. 4, lines 20-22.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen.

16. For Claim 6, Cohen teaches all the limitations of Claim 5, as indicated above in paragraph 9. Cohen teaches the compression ring being an elastic band (compression member 62, col. 4, lines 35-36). For Claim 6, Cohen does **not** expressly teach the compression ring being made of a metal, polymer, or spring steel material. It is well known in the catheter art that elastic bands may be manufactured from polymers. It would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to make the elastic band of a polymer material, to provide for elasticity.

17. Claims 8 and 9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as being unpatentable over **either** Cohen or Schwartz, each one individually.

For Claims 8 and 9, Cohen and Schwartz each teach all the limitations of Claim 1, as indicated above in paragraphs 5 and 11. Both Cohen and Schwartz are silent as to hardness of the compression sleeve and the catheter tube. As to anticipation, absent evidence to the contrary, the compression sleeves and catheter tubes taught by either Cohen or Schwartz are presumed to have Applicant's claimed hardness values. Applicant's claimed ranges are considered by the Examiner to be inherent in either Cohen or Schwartz. As to obviousness, for the compression sleeve the hardness is a result effective variable, since it affects the amount of force needed to compress the

catheter tube, as well as the durability of the compression sleeve in use. For the catheter tube the hardness or Shore A value is a result effective variable, since it affects the amount of force from the compression sleeve needed to collapse the tube and resistance to kinking, as well as the durability of the tube in use. The discovery of an optimum value of a result effective variable is ordinarily within the ordinary skill in the art. See *In re Boesch and Slaney,* 205 USPQ 215 (CCPA 1980). Materials having the claimed hardness ranges are known in the catheter art for making compression sleeves and catheter tubes. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the catheters of either Cohen or Schwartz to include the claimed hardness values.

18. Claim 10 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as being unpatentable over Schwartz.

19. For Claim 10, Schwartz teaches all the limitations of Claim 9, as indicated above in paragraph 18. Schwartz teaches the compression sleeve being made from a silicone material (col. 3, lines 49-51). Schwartz teaches the catheter tube being made from urethane (collapsible membrane 22, col. 4, lines 18-23). Schwartz is silent as to the claimed hardness or Shore A values. As to anticipation, absent evidence to the contrary, the compression sleeve and catheter tube taught by Schwartz are presumed to have Applicant's claimed hardness values. Applicant's claimed ranges are considered by the Examiner to be inherent in Schwartz. As to obviousness, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify

the catheter of Schwartz to include the claimed hardness values, since hardness is a result effective variable, as indicated above in paragraph 18.

Conclusion

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 4,946,449 to Davis, Jr. shows a catheter tube in which the lumen is biased closed, but assumes an open position when an attachable unit is inserted in the valve. U.S. Patent No. 5,158,545 to Trudell et al. shows a catheter tube having a necked portion. The article "Care of the Groshong Catheter" by L. Dawn Camp, Oncol. Nurs. Forum, pages 745-748, Vol. 15, No. 6, 1988, teaches that catheters having single, double, or triple lumens are well known in the art. The remaining prior art references listed on the accompanying Form PTO-892 show the general state of the art.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paula L. Craig whose telephone number is (571)272-5964. The examiner can normally be reached on 8:30AM-5:00PM M-F.

22. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571)272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

23. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paula L Craig
Examiner
Art Unit 3761

PLC

TATYANA ZALUKAEVA
PRIMARY EXAMINER